

Table 1

Parameter	No. of process batches				
	9002	9003	0001	0002	0003
Protein (%)	4.6	4.5	4.7	4.8	N.D.
Turbidity (NTU)	3.3	3.3	3.0	3.1	2.8
Sorbitol (%)	4.75	4.85	4.9	N.D.	N.D.
Purity (%)	100	99.2	99.7	99.8	99.9
Polymer (%)	0	0	0	0	0
Fractions (%)	0	0	0	0	0
PEG (ppm)	164	311	224	N.D.	N.D.
Polysorbate (ppm)	<30	<30	34	<30	40
TNBP (ppm)	<3.6	<3.6	<3.6	<3.6	<3.6
PKA (IU/ml)	<2.8	<2.8	<2.8	<2.8	<2.8
ACA (CH50/mg Ig)	0.68	0.76	0.75	0.66	0.63
IgA (mg/ml)	<0.003	<0.003	<0.003	<0.003	<0.003
IgM (mg/ml)	<0.002	<0.002	<0.002	<0.002	<0.002

Delete, in its entirety, Table 3 on page 32 of the specification as filed and insert, in its place the following replacement Table 3 with the changes indicated at Exhibit Tab A:

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Table 3

Process No.	No. of Washing Volumes (in the TFF)	Concentration of Polysorbate in final product 5% IVIG (ppm)
9003	5	<30
8006	4	50
8007	2.5	200

Delete, in its entirety, Table 6 on page 38 of the specification as filed and insert, in its place the following replacement Table 6 with the changes indicated at Exhibit Tab A:

A3

Table 6

BATCH No.	% OF POLYMERS (OR HIGH MOLECULAR WEIGHT AGGREGATES)			TURBIDITY (NTU)	
	Before pasteurising	After pasteurising	After SD	Before Pasteurising	After pasteurising
9002	n.d.	1.23	N.D.	1.5	1.6
9003	n.d.	1.16	1.97	1.4	1.8
0001	n.d.	1.04	1.19	5.9	1.8
0002	n.d.	1.21	1.30	2.3	2.4
0003	n.d.	1.35	1.15	1.7	2.0

Delete, in its entirety, Table 7 on page 40 of the specification as filed and insert, in its place the following replacement Table 7 with the changes indicated at Exhibit Tab A:

Table 7

LOADING RATIO (g of fraction II+III / ml of resin)	LOADING TIME (hours)	PURITY OF EFFLUENT (electrophoresis)		(%) RECOVERY OF GAMMAGLO- BULIN (2)
		Albumin (1)	gamma (%)	
4.0	12.15	(+)	97.2	97
2.5		(-)	98.7	95
2.25		(-)	98.3	105
1.25		(-)	97.7	97
0.875		(-)	100	98
0.625		(-)	100	100
1.65		(+++)	85.6	n.d.

Delete, in its entirety, Table 9 on page 43 of the specification as filed and insert, in its place the following replacement Table 9 with the changes indicated at Exhibit Tab A:

Table 9

A5

SORBITOL (%)	PROTEIN (%)	Adjustment to pH 4.0 at 20°C-25°C		Adjustment to pH 4.0 at 2°C-8°C
		Aggregates % (after incubation at pH 4)	Aggregates % (after pasteurising)	Aggregates % (after incubation at pH 4)
5	0.25	N.D.	N.D.	n.d.
5	1	0.31	0.57	n.d.
5	2	0.34	0.64	N.D.
5	2.5	N.D.	N.D.	n.d.
5	3	0.37	1.01	N.D.
5	4	0.93	1.57	N.D.
5	5	0.83	1.81	0.43
5	5	0.86	3.50	
10	5	0.15	0.83	
20	5	0.10	N.D.	
33	5	n.d.	0.70	

Delete, in its entirety, Table 10 on page 45 of the specification as filed and insert, in its place the following replacement Table 10 with the changes indicated at Exhibit Tab A:

Table 10

SORBITOL (%)	PROTEIN (%)	TIME AT pH 4 (hours)	Aggregates % (after treatment at pH 4)	Aggregates % (after pasteurisation)
5	2.5	1	n.d.	0.35
5	2.5	2	0.30	0.59
5	2.5	4	n.d.	0.32
6	3	0	0.11	0.36
6	3	1	0.07	0.31
6	3	4	0.07	0.41
6	3	8	0.40	1.11
6	3	12	0.43	1.18
6	3	24	0.15	0.58

A6
Delete, in its entirety, Table 11 on page 46 of the specification as filed and
insert, in its place the following replacement Table 11 with the changes indicated at
Exhibit Tab A:

Table 11

(%) PROTEIN	pH	(%) POLYMERS	(%) DIMERS
2.5	5.52	0.46	4.36
2.5	5.03	0.35	3.49
2.5	4.72	0.30	3.31
2.5	4.51	0.45	3.34
5	4.2	4.89	4.54
5	4.0	14.42	5.60
5	3.8	24.51	6.23